

Ser. No. 10/802,712

PATENT
03P04138US01**REMARKS**

Claims 1, 3, 9, 11, 15, 17 and 20-24 are amended to correct typographical errors and to more clearly define the invention.

Support for these amendments is found in the existing claims and in the Application in connection with Figure 1 and other places.

I. Drawings.

New Formal Drawings are enclosed herein satisfying the objections. Consequently this ground of objection is no longer deemed applicable and its withdrawal is respectfully requested.

II. Objection to the Specification.

The Abstract is objected to as containing "addresses" instead of "address". The Abstract has been amended accordingly. Consequently this ground of objection is no longer deemed applicable and its withdrawal is respectfully requested.

III. Claim Objections.

Claim 15 is objected to as omitting a period. Claim 15 has been amended accordingly. Consequently this ground of objection is no longer deemed applicable and its withdrawal is respectfully requested.

IV. Rejection under 35 U.S.C. 102(e)

Claims 1-5, 9-11, 13, 14 and 17-25 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application 2002/0107641—Schaeffer et al. These claims are deemed to be patentable for the reasons given below.

Claim 1 recites a system for "processing information related to laboratory tests and results" comprising "an interface processor for receiving user entered data identifying a laboratory test result of a patient specimen culture and for receiving user entered data identifying an expected result of said laboratory test and data identifying a validation pre-condition; a validation processor for employing one or more user determined validation pre-conditions in comparing said laboratory test

Ser. No. 10/802,712

PATENT
03P04138US01

result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result; and a result processor for initiating generation of an alert message to a user indicating said first failure condition". These features are not shown (or suggested) in Schaeffer.

The laboratory test result processing system of claim 1 receives "user entered data identifying a laboratory test result of a patient specimen culture" and "user entered data identifying an expected result of said laboratory test and data identifying a validation pre-condition". A "validation processor" employs "one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result" and identifies a "first failure condition in response to said laboratory test result failing to match said expected test result". These features are not show or suggested in Schaeffer or the other cited references. The claimed system "addresses the need for an improved microbiology validation system. During a culture's "testing lifecycle" in a clinical micro-biology laboratory, numerous results are entered and released over a course of hours, days or weeks". The system "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2 lines 24-29). The system advantageously performs "validations of test cultures by continuously monitoring and comparing test results as they occur with previously obtained test results throughout the lifecycle of a culture. A further advantage provided by the invention is a capability to monitor test results that are entered throughout the lifecycle of a culture. The invention also advantageously considers specific quantities when defining expected results and alerts a user of unexpected results prior to their release to a physician for review. A still further advantage allows a user to define who can override a validation failure" (Application page 3 line 29 to page 4 line 4). The claimed features as well as associated problems addressed and advantages are not recognized or contemplated in Schaeffer.

Schaeffer does NOT show or suggest "receiving user entered data identifying a laboratory test result of a patient specimen culture" and "receiving user entered data identifying an expected result of said laboratory test and data identifying a validation pre-condition" and "a validation processor for employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result". Schaeffer "teaches the use of data mining approaches to better predict the pathogen encountered

Ser. No. 10/802,712

PATENT
03P04138US01

and to provide better medical practitioner guidance with respect to the undiagnosed patient. This is particularly crucial within this application since susceptibilities and tolerance to pathogen mutations and their treatment rapidly change" (Schaeffer para. 0035). Schaeffer is concerned with the management of predicted diseases in patients with specific symptoms. The predictions are based on the historical epidemiological data such as epidemiology profiles, patient demographics and similar symptoms and are used to suggest courses of treatment. Schaeffer describes how the historical data is entered into the system (para. 0049, 0050), and how the data can be cleaned i.e. to remove patient specific identification information (para. 0072) and how the data can be retrieved and sorted (para. 0087).

Schaeffer, contrary to the Rejection statements on page 4 does not show or suggest in para. 0044 or elsewhere "receiving user entered data identifying a laboratory test result of a patient specimen culture" and "receiving user entered data identifying an expected result of said laboratory test and data identifying a validation pre-condition". Schaeffer in para. 0044 merely indicates "The present invention thus allows prediction, or diagnosis, for the particular patient" which "may preferably be done for the patient prior to, or in the absence of, obtaining a sample, and analyzing the sample, from the particular patient". Schaeffer paragraph 0044 advocates prediction of diagnosis without "receiving user entered data identifying a laboratory test result" and certainly provides no suggestion at all of "receiving user entered data identifying an expected result of said laboratory test and data identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result".

Schaeffer teaches data mining of historical epidemiological data may be used to predict a pathogen and does NOT suggest user entry of "data identifying an expected result" of a "laboratory test". On the contrary, the Schaefer method is intended to be performed prior to, or in the absence of, a culture (Para. 0044) and consequently is wholly independent of a "laboratory test". In addition, Schaeffer in paragraphs 0052, 0056 or elsewhere does not suggest a user interface for "receiving" "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result". There is no mention, in para. 0056, 0074 or elsewhere in Schaeffer of a "pre-

Ser. No. 10/802,712

PATENT
03P04138US01

condition" at all and no suggestion of a user interface for "receiving" "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result".

Schaeffer in para. 0056 mentions a determination "if the identity of the antimicrobial is provided" of a "person's outcome at the completion of the course of treatment" and "whether the antimicrobial is effective for treating the identified bacterium. That is, whether the symptoms are resolved by completion of the course of antimicrobial treatment is an indicator as to whether the antimicrobial taken is effective in treating the bacterial infection". However, whether or not a course of antimicrobial treatment is effective in treating a patient has nothing to do with whether or not a "laboratory test result" meets user entered "pre-condition" criteria. A treatment outcome is NOT (and does not suggest) a "laboratory test result". Consequently, Schaeffer fails to suggest a user interface for "receiving" "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result". Paragraph 0074 of Schaeffer relied on in the Rejection on page 4 concerns "data cleaning" and has no bearing on "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result".

Schaeffer in para. 0087 relied on in the Rejection on page 4 also fails to show or suggest a "result processor for initiating generation of an alert message to a user indicating" a "first failure condition". Paragraph 0087 merely discusses generation of reports from a database and provides no 35 USC 112 compliant enabling disclosure of "initiating generation of an alert message to a user indicating" a "first failure condition" derived by employing "validation pre-conditions in comparing said laboratory test result with said expected test result". Schaeffer is not concerned with facilitating the operation of laboratory testing or of providing a system that "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2 lines 24-29). On the contrary Schaeffer discloses a function that is performed prior to, or in the absence of, a culture (Para. 0044) and consequently is wholly independent of a "laboratory test".

Ser. No. 10/802,712

PATENT
03P04138US01

The Schaeffer system "relates to the management of diagnosis and treatment of infections prior to or in the absence of culturing the pathogen prior to commencing treatment" (para. 0002). In contrast, the claimed system "addresses the need for an improved microbiology validation system. During a culture's "testing lifecycle" in a clinical micro-biology laboratory" (Application page 2 lines 24-29). Schaeffer teaches the use of data mining for prediction of pathogens, diagnosis or treatment prior to or in the absence of culturing the pathogen whereas the claimed system supports the identification of causative pathogens that have been recovered and isolated from patient cultures. The Schaeffer and claimed systems are fundamentally different address different problems and Schaefer fails to show or suggest the claimed arrangement. Consequently, withdrawal of the Rejection of claim 1 under 35 U.S.C. 102(e) based on Schaeffer is respectfully requested.

Dependent claim 2 is considered to be patentable based on its dependence on claim 1 and for reasons given in connection with claim 1. Claim 2 is also considered to be patentable because Schaeffer does not show (or suggest) a system including an "interface processor" that "further receives user entered data identifying at least one further laboratory test result of said patient and user entered data identifying at least one further expected laboratory test result of said at least one further laboratory test; and wherein said validation processor compares said at least one further laboratory test result with said at least one further expected laboratory test result and identifies a second failure condition in response to said at least one further laboratory test result of said patient failing to match said at least one further expected laboratory test result; and wherein said result processor initiates generation of an alert message to a user indicating said second failure condition". As previously explained in connection with claim 1, Schaeffer discloses a function that is performed prior to, or in the absence of, a culture (Para. 0044) and consequently is wholly independent of a "laboratory test".

Schaeffer provides no 35 USC 112 compliant enabling disclosure of "initiating generation of an alert message to a user indicating" a "second failure condition" derived when "said validation processor compares said at least one further laboratory test result with said at least one further expected laboratory test result and identifies a second failure condition in response to said at least one further laboratory test result of said patient". Schaeffer nowhere suggests any comparison of an individual laboratory test result with an expected laboratory test result and certainly not a multiple test comparison involving a "validation processor" that

Ser. No. 10/802,712

PATENT
03P04138US01

"compares said at least one further laboratory test result with said at least one further expected laboratory test result and identifies a second failure condition in response to said at least one further laboratory test result".

Amended dependent claim 3 is considered to be patentable based on its dependence on claim 1 for reasons given in connection with claim 1. Claim 3 is also considered to be patentable because Schaeffer does not show (or suggest) a system in which an "interface processor further receives user entered data identifying a plurality of validation pre-conditions for validating said laboratory test of said patient; wherein said validation processor identifies a second failure condition when at least one of said plurality of validation pre-conditions are not satisfied; and wherein said result processor initiates generation of an alert message to a user indicating said second failure condition". As previously explained in connection with claim 1, Schaeffer discloses a function that is performed prior to, or in the absence of, a culture (Para. 0044) and consequently is wholly independent of a "laboratory test".

Schaeffer provides no 35 USC 112 compliant enabling disclosure of an "interface processor" that "further receives user entered data identifying a plurality of validation pre-conditions for validating said laboratory test of said patient; wherein said validation processor identifies a second failure condition when at least one of said plurality of validation pre-conditions are not satisfied. Schaeffer also fails to suggest "initiating generation of an alert message to a user indicating" a "second failure condition" derived when "when at least one of said plurality of validation pre-conditions are not satisfied". Schaeffer nowhere suggests any comparison of an individual laboratory test result with an expected laboratory test result and not a test comparison involving a "plurality of validation pre-conditions" that "identifies a second failure condition when at least one of said plurality of validation pre-conditions are not satisfied". Whether or not a course of antimicrobial treatment is effective in treating a patient (para. 0056 relied upon in the Rejection on page 4) has nothing to do with whether or not a "laboratory test result" meets user entered "pre-condition" criteria.

Dependent claim 4 is considered to be patentable based on its dependence on claim 1. Claim 4 is also considered to be patentable because Schaeffer does not show (or suggest) a system in which "said received user entered data identifying an expected result of said laboratory test comprises at least one of, (a) an identifier indicating a culture is resistant to a test compound, (b) an identifier

Ser. No. 10/802,712

PATENT
03P04138US01

indicating a culture is sensitive to a test compound, (c) an identifier indicating a positive test result and (d) an identifier indicating a negative test result". As previously explained in connection with claim 1, Schaeffer discloses a function that is performed prior to, or in the absence of, a culture (Para. 0044) and consequently is wholly independent of a "laboratory test" and fails to show or suggest in para. 0056 or elsewhere employing "user entered data identifying an expected result of said laboratory test".

Dependent claim 5 is considered to be patentable based on its dependence on claim 1. Claim 5 is also considered to be patentable because Schaeffer does not show (or suggest) a system in which "said received user entered data identifying an expected result of said laboratory test comprises a quantity identifier indicating presence of an approximate quantity of microbes per unit area of a culture". As previously explained in connection with claim 1, Schaeffer discloses a function that is performed prior to, or in the absence of, a culture (Para. 0044) and consequently is wholly independent of a "laboratory test". Schaeffer fails to show or suggest in para. 0053 or elsewhere employing "user entered data identifying an expected result of said laboratory test comprises a quantity identifier indicating presence of an approximate quantity of microbes per unit area of a culture". The "detectable amounts of bacteria" in para. 0053 relied upon in the Rejection on page 5 has no bearing on employing "user entered data identifying an expected result of said laboratory test" that comprises "a quantity identifier indicating presence of an approximate quantity of microbes per unit area of a culture". No such "quantity identifier" is suggested in Schaeffer.

Dependent claim 7 is considered to be patentable based on its dependence on claims 1 and 5. Claim 7 is also considered to be patentable because Schaeffer does not show (or suggest) the feature combination of claim 7 in which "said microbes comprise at least one of, (a) a bacteria, (b) a fungi, (c) a parasite and (d) a virus".

Amended dependent claim 9 is considered to be patentable based on its dependence on claim 1. Claim 9 is also considered to be patentable because Schaeffer does not show (or suggest) a system in which "said received user entered data identifies a plurality of expected results of said laboratory test and said validation processor compares a plurality of laboratory test results with said plurality of expected results and identifies a failure condition in response to a predetermined condition if at least one of said plurality of laboratory test results fails to match a corresponding one

Ser. No. 10/802,712

PATENT
03P04138US01

of said plurality of expected results". As previously explained in connection with claim 1, Schaeffer discloses a function that is performed prior to, or in the absence of, a culture (Para. 0044) and consequently is wholly independent of a "laboratory test". Schaeffer fails to show or suggest in para. 0044, 0059 or elsewhere, employing "received user entered data" that "identifies a plurality of expected results of said laboratory test" and comparing "a plurality of laboratory test results with said plurality of expected results" and identifying "a failure condition in response to a predetermined condition if at least one of said plurality of laboratory test results fails to match a corresponding one of said plurality of expected results".

Dependent claim 10 is considered to be patentable based on its dependence on claim 1. Claim 10 is also considered to be patentable because Schaeffer does not show (or suggest) a system in which "said interface processor receives user entered data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test, said validation processor compares an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results and identifies a failure condition in response to said individual laboratory test result failing to match said corresponding expected test result; and said result processor initiates generation of an alert message to a user indicating a failure condition of said individual test performed at a particular time stage of said different time stages". Schaeffer in para. 0044 merely indicates "The present invention thus allows prediction, or diagnosis, for the particular patient" which "may preferably be done for the patient prior to, or in the absence of, obtaining a sample, and analyzing the sample, from the particular patient". Schaeffer paragraph 0044 advocates prediction of diagnosis without "receiving user entered data identifying a laboratory test result" and certainly provides no suggestion at all of "receives user entered data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test" and comparing "an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results".

Further, Schaeffer in para. 0087 relied on in the Rejection on page 5 also fails to show or suggest "initiating generation of an alert message to a user indicating" a "failure condition". Paragraph 0087 merely discusses generation of reports from a database and provides no 35 USC 112 compliant enabling disclosure of such a feature. Schaeffer is not concerned with facilitating the operation of laboratory testing or of providing a system that "improves upon this process by

Ser. No. 10/802,712

PATENT
03P04138US01

providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2 lines 24-29). On the contrary Schaeffer discloses a function that is performed prior to, or in the absence of, a culture (Para. 0044) and consequently is wholly independent of a "laboratory test".

Dependent claim 11 is considered to be patentable based on its dependence on claim 1. Claim 11 is also considered to be patentable because Schaeffer does not show (or suggest) a system in which "said result processor initiates generation of an alert message to a user in response to occurrence of said failure condition, said message at least one of, (a) prompting a user to initiate performance of another predetermined laboratory test, (b) informing a user of potential reasons for said failure condition, (c) prompting a user to repeat said laboratory test, (d) prompting a user with a user predetermined message and (e) identifying an expected result and actual result of said laboratory test". Schaeffer in para. 0087 relied on in the Rejection on page 6 fails to show or suggest "initiating generation of an alert message to a user indicating" a "failure condition". Paragraph 0087 merely discusses generation of reports from a database and provides no 35 USC 112 compliant enabling disclosure of such a feature. Schaeffer is not concerned with facilitating the operation of laboratory testing or of providing a system that "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2 lines 24-29). On the contrary Schaeffer discloses a function that is performed prior to, or in the absence of, a culture (Para. 0044) and consequently is wholly independent of a "laboratory test". of said plurality of test results".

Dependent claim 13 is considered to be patentable based on its dependence on claim 1. Claim 13 is also considered to be patentable because Schaeffer does not show (or suggest) a system in which "said result processor initiates generation of an alert message to a user prompting a user to enter an override command indicating whether said failure condition is to be overridden". Schaeffer in para. 0090 relied on in the Rejection on page 6 fails to show or suggest initiating "generation of an alert message to a user prompting a user to enter an override command indicating whether said failure condition is to be overridden". Paragraph 0090 merely discusses generation of reports from a database and provides no 35 USC 112 compliant enabling disclosure of such a feature and no mention or suggestion of overriding a command at all.

Ser. No. 10/802,712

PATENT
03P04138US01

Dependent claim 14 is considered to be patentable based on its dependence on claim 1. Claim 14 is also considered to be patentable because Schaeffer does not show (or suggest) a system in which "said result processor initiates storage of a record indicating said failure condition was overridden, in response to said user override command, said record at least one of, (a) being accessible by an authorized person, (b) providing an audit trail indicating a person entering said override command and (c) being incorporated in a report identifying override command occurrences". Schaeffer in para. 0090 relied on in the Rejection on page 6 merely discusses generation of reports from a database and provides no 35 USC 112 compliant enabling disclosure of such a feature and no mention or suggestion of overriding a command at all.

Dependent claim 19 is considered to be patentable based on its dependence on claim 1. Claim 19 is also considered to be patentable because Schaeffer does not show (or suggest) a system in which "said at least one display image includes display elements for displaying an alert message to a user prompting a user to enter an override command indicating whether said failure condition is to be overridden". Schaeffer in para. 0090 relied on in the Rejection on page 6 fails to show or suggest "said at least one display image includes display elements for displaying an alert message to a user prompting a user to enter an override command indicating whether said failure condition is to be overridden". Paragraph 0090 merely discusses generation of reports from a database and provides no 35 USC 112 compliant enabling disclosure of such a feature and no mention or suggestion of overriding a command at all.

Independent claims 17 and 20-24 are considered to be patentable for reasons given in connection with claim 1 and other described claims and for additional reasons.

Dependent claim 18 is considered to be patentable for reasons given in connection with claims 1, 4 and 5 and for additional reasons.

Dependent claim 25 is considered to be patentable for reasons given in connection with claim 1 and other described claims and for additional reasons.

Ser. No. 10/802,712

PATENT
03P04138US01

Consequently, withdrawal of the Rejection of claims 1-5, 9-11, 13, 14 and 17-25, under 35 U.S.C. 102(e) as being anticipated by Schaeffer is respectfully requested.

V. Rejection under 35 U.S.C. 103(a)

Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application 2002/0107641- Schaeffer et al. in view of U.S. Patent 5,789,173 - Peck. These claims are deemed to be patentable for the reasons given below.

Dependent claim 6 is considered to be patentable based on its dependence on claims 1 and 5. Claim 6 is also considered to be patentable because Schaeffer and Peck, individually or in combination, do not show (or suggest) the combination of features of claim 6 in which "said quantity identifier identifies a qualitative range of said quantity of microbes per unit area, including at least one of, (a) an identifier indicating "few" and (b) an identifier indicating "many".

Neither Schaeffer nor peck alone or together, show or suggest a user interface for "receiving" "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result". Schaeffer, as recognized in the Rejection, fails to show or suggest "a qualitative range of said quantity of microbes per unit area, including at least one of, (a) an identifier indicating "few" and (b) an identifier indicating "many". However, contrary, to the Rejection statement on page 7, Peck in column 3 lines 35-46 merely states that bacterial and inoculation concentrations may vary. Peck (with Schaeffer) fails to suggest employing "user entered data identifying an expected result of said laboratory test" that comprises "a quantity identifier" identifying "a qualitative range" comprising a "quantity of microbes per unit area, including at least one of, (a) an identifier indicating "few" and (b) an identifier indicating "many". The "detectable amounts of bacteria" in para. 0053 of Schaeffer relied upon in the Rejection in connection with claim 5 and the varying inoculation concentrations of Peck fail to suggest employing "user entered data identifying an expected result of said laboratory test" that "comprises a quantity identifier" identifying "a qualitative range" comprising a "quantity of microbes per unit area, including at least one of, (a) an identifier indicating "few" and (b) an identifier indicating "many". No such

Ser. No. 10/802,712

PATENT
03PO4138US01

"quantity identifier" for use in entering an expected laboratory test result via a laboratory test system user interface is suggested in Schaeffer or Peck alone or together.

Further, employing the Peck varying bacterial and inoculation concentration in Schaeffer results in a system using data mining approaches to better predict the pathogen encountered and to provide better medical practitioner guidance with respect to the undiagnosed patient based on the historical epidemiological data such as epidemiology profiles, patient demographics, data indicating varying bacterial and inoculation concentrations and similar symptoms and are used to suggest courses of treatment. Such a system fails to show or suggest a user interface for "receiving" "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result". Also, since Schaeffer and Peck, alone or together, fail to recognize or address the specific problem of facilitating the operation of laboratory testing or of providing a system that "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2 lines 24-29), neither Schaeffer nor Peck contain any motivation or other reason for incorporating the features of the claimed arrangement. The Schaeffer with Peck system is entirely separate and independent from a laboratory test system and user interface.

Dependent claim 8 is considered to be patentable based on its dependence on claim 1 for reasons given in connection with claims 1 and 6. Claim 8 is also considered to be patentable because Schaeffer and Peck, individually or in combination, do not show (or suggest) the combination of features of claim 8 in which "said received user entered data identifying an expected result of said laboratory test identifies at least one of, (a) a count value of number of microbes present per unit area of a culture, (b) a color of a microbe indicator, (c) a color change of a microbe indicator".

Neither Schaeffer nor peck alone or together, show or suggest a user interface for "receiving" "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure

Ser. No. 10/802,712

PATENT
03P04138US01

condition in response to said laboratory test result failing to match said expected test result". Schaeffer, as recognized in the Rejection, fails to show or suggest "an expected result of said laboratory test identifies at least one of, (a) a count value of number of microbes present per unit area of a culture, (b) a color of a microbe indicator, (c) a color change of a microbe indicator". However, contrary, to the Rejection statement on page 7, Peck in column 3 lines 18-34 merely states that bacterial and inoculation concentrations may vary. Peck (with Schaeffer) fails to suggest use of user entered data indicating "an expected result of said laboratory test" that "identifies...a count value of number of microbes present per unit area of a culture". Neither Peck nor Schaeffer suggest use of user entered data indicating such "an expected result of said laboratory test". Also, since Schaeffer and Peck, alone or together, fail to recognize or address the specific problem of facilitating the operation of laboratory testing or of providing a system that "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2 lines 24-29), neither Schaeffer nor Peck contain any motivation or other reason for incorporating the features of the claimed arrangement.

Consequently, withdrawal of the Rejection of claims 6 and 8 under 35 U.S.C. 103(a) is respectfully requested.

VI. Rejection under 35 U.S.C. 103(a)

Claims 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application 2002/0107641- Schaeffer et al. in view of U.S. Patent 6,830,731 - Buechler et al. These claims are deemed to be patentable for the reasons given below.

Dependent claim 12 is considered to be patentable based on its dependence on claims 1 and 3. Claim 12 is also considered to be patentable because Schaeffer and Buechler, individually or in combination, do not show (or suggest) the combination of features of claim 12 in which "one of said plurality of validation preconditions corresponds to an elapsed time period to wait before comparing said laboratory test result with said expected test result, said elapsed time period being a time period following initiation of said laboratory test".

Ser. No. 10/802,712

PATENT
03P04138US01

Neither Schaeffer nor Buechler alone or together, show or suggest a user interface for "receiving" "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result". Schaeffer, as recognized in the Rejection, fails to show or suggest "one of said plurality of validation preconditions corresponds to an elapsed time period to wait before comparing said laboratory test result with said expected test result, said elapsed time period being a time period following initiation of said laboratory test". However, contrary, to the Rejection statement on page 8, Buechler in column 12 lines 32-39 merely states that timing of an assay test may be controlled. Buechler (with Schaeffer) fails to suggest employing "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions" including "an elapsed time period to wait before comparing said laboratory test result with said expected test result, said elapsed time period being a time period following initiation of said laboratory test" in "comparing said laboratory test result with said expected test result".

Further, employing the Buechler assay timing in Schaeffer results in a system using data mining approaches to better predict the pathogen encountered and to provide better medical practitioner guidance with respect to the undiagnosed patient based on the historical epidemiological data such as epidemiology profiles derived using timed assay tests, patient demographics, and similar symptoms and are used to suggest courses of treatment. Such a system fails to show or suggest a user interface for "receiving" "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result". Also, since Schaeffer and Buechler, alone or together, fail to recognize or address the specific problem of facilitating the operation of laboratory testing or of providing a system that "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2 lines 24-29), neither Schaeffer nor Buechler contain any motivation or other reason for incorporating the features of the claimed arrangement.

Ser. No. 10/802,712

PATENT
03P04138US01

Amended dependent claim 15 is considered to be patentable based on its dependence on claim 1 for reasons given in connection with claims 1 and 8. Claim 15 is also considered to be patentable because Schaeffer and Buechler, individually or in combination, do not show (or suggest) the combination of features of claim 15 including "an authorization processor for determining whether a user is authorized to override said failure condition and to inhibit override in response to a determination said user is unauthorized". Contrary to the Rejection statement on page 9, Buechler in column 9 lines 11-16 discusses user accessibility for purposes of changing fluorometer parameters and NOT to "inhibit override" of a determined "failure condition" in "response to a determination said user is unauthorized". Incorporating the identified feature in Buechler fails to show or suggest the claimed arrangement. Also, since Schaeffer and Buechler, alone or together, fail to recognize or address the specific problem of facilitating the operation of laboratory testing or of providing a system that "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2 lines 24-29), neither Schaeffer nor Buechler contain any motivation or other reason for incorporating the features of the claimed arrangement.

Consequently, withdrawal of the Rejection of claims 12 and 15 under 35 U.S.C. 103(a) is respectfully requested.

VII. Rejection under 35 U.S.C. 103(a)

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application 2002/0107641— Schaeffer et al. in view of U.S. Patent 6,753,186 — Moskoff. This claim is deemed to be patentable for the reasons given below.

Dependent claim 16 is considered to be patentable based on its dependence on claim 1. Claim 16 is also considered to be patentable because Schaeffer and Buechler, individually or in combination, do not show (or suggest) the combination of features of claim 16 in which "said result processor initiates generation of an alert message with a plurality of different warning severity message levels".

Neither Schaeffer nor Moskoff alone or together, show or suggest a user interface for "receiving" "user entered data" "identifying a validation pre-

Scr. No. 10/802,712


PATENT
03P04138US01

condition" and "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result". Schaeffer, as recognized in the Rejection, fails to show or suggest "said result processor initiates generation of an alert message with a plurality of different warning severity message levels". Contrary, to the Rejection statement on page 9, Moskoff in column 14 line 55 to column 15 line 10 merely discusses water quality testing. Moskoff (with Schaeffer) fails to suggest employing "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions" in "comparing said laboratory test result with said expected test result" and initiating "generation of an alert message with a plurality of different warning severity message levels". Further Moskoff concerns water quality monitoring and is non-analogous art. One of ordinary skill in the art of laboratory equipment user interface systems would not be prompted to look to the field of water quality monitoring and treatment. Consequently, withdrawal of the Rejection of claim 1-25 is respectfully requested.

In view of the above amendments and remarks, applicant submits that this application is in condition for allowance, and favorable reconsideration is requested.

Respectfully submitted,

Date: October 12, 2005



Alexander J. Burke
Reg. No. 40,425

Siemens Corporation,
Customer No. 28524
Tel. 732 321 3023
Fax 732 321 3030